S/N Unknown **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	M. Zafar A. Munshi	Examiner: Unknown
Serial No.:	Unknown (Parent: 09/042,255)	Group Art Unit: Unknown
Filed:	Herewith	Docket: 1080.165US3
Title:	AN IONICALLY CONDUCTIVE POLYMERIC COMPOSITION (as amended)	

PRELIMINARY AMENDMENT

BOX PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This is a Divisional Application of S/N 09/042,255, in response to the Restriction Requirement mailed July 19, 1999. Please amend the application as follows:

In the Drawings

Applicant requests voluntary drawing amendments for Figs. 1A, 1B, 2A, 4 and 5 as marked in red on a photocopy of the drawing enclosed. Formal drawings reflecting these amendments are included as replacement drawings.

For Figs. 1A, 1B and 4, "(Prior Art)" has been added to the caption.

For Fig. 2A, elements 102 and 120 have been changed to 100 and 106, respectively, to correct mismarked elements, and element 104 has been deleted.

For Fig. 5, element 80 has been added to identify an unmarked element.

In the Title

Please amend the title to read --AN IONICALLY CONDUCTIVE POLYMERIC COMPOSITION --.

Page 1, line 1, please delete "BACKGROUND OF THE INVENTION", and insert therefore the following:

-- CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. Serial No. 09/042,255 filed March 13, 1998, entitled Defibrillator Housing With Conductive Polymer Coating, the specification of which is hereby incorporated by reference. This application is also related to U.S. Serial No. 09/793,000, entitled Method of Making a Stimulator Electrode With A Conductive Polymer Coating, filed on February 26, 2001, also a divisional of U.S. Serial No. 09/042,255, said application hereby incorporated by reference. --

Please replace the paragraph beginning on page 18, line 22 with the following rewritten paragraph:

An improvement over known titanium electrodes, including "hot can" electrodes such as that disclosed in the '607 patent, is provided by the present invention by increasing the effective surface area of the electrode, overlaying this roughened, or enhanced, substrate with a thin coating comprising a conductive polymer. FIG. 2B illustrates, in partial cut-away, view of the tissue/can interface of a polymer coated can 1 in accordance with the present invention. A conventional defibrillator unit 1, having a titanium housing 10 coated with an insulative material 12, such as parylene, and an uncoated area or window 14 in coating 12, includes an etched, or otherwise surface area enhanced, titanium surface 100 that functions as one of the stimulus electrodes. Over titanium surface 100 is a high surface area noble metal layer 106. Permeating and overlying noble metal layer 106 is a conductive polymeric coating 70 that has a smooth outer surface 90, as best show in enlarged detail in FIG. 2A. The coated unit is prepared as follows. First, the surface area is increased by highly etching the titanium can surface with acid, such as oxalic acid at 80EC for one to two hours, as previously described in U.S. Pat. No. 5,645,030 ("the '030 patent") for transvenous electrodes, the disclosure of which is incorporated herein by reference. In this way, the surface area of the substrate is increased by as much as 20 times over the planar surface area of the original can. Next, a very thin stable coating of electrode material,

such as platinum, is deposited on the etched substrate in such a way that the platinum layer literally follows the contours of the etched pattern, or porous structure. This is accomplished by ion beam deposition, sputtering, evaporation, plasma spraying, chemical methods, or other means. Care is taken to make the platinum layer continuous but not so thick that it fills in the voids, or completely blocks the etched pattern with the coating material. In this way a high surface area platinum is generated which retains a great deal of the original surface roughness. Although the preferred coating material is platinum, another similarly stable electrode material, such as ruthenium, rhodium, palladium, osmium, iridium, or an alloy of any of those metals, could be substituted with good results.

Please replace the paragraph beginning on page 25, line 28 with the following rewritten paragraph:

Fig. 4 is an enlarged detailed illustration fo the can/tissue interface with a conventional IrOx coat 80 adheres to the surface of the titanium housing 10, making up interface 20 between the titanium surface 100 and the adjacent body tissue 30. For porous can surfaces such as a titanium can coated with an oxide such as IrOx, problems of poor interfacial contact with the tissue will occur, similar to the situation for bare titanium cans after repeated shocks. To address this problem, the conductive polymeric coating of the present invention was devised for filing the interstices of the IrOx coating and providing a smooth tissue interface. FIG. 2B illustrates, in partial cut-away, a can 1 produced in accordance with the 80 and the polymeric coating 70 of the present invention.

Please replace the paragraph beginning on page 30, line 6 with the following rewritten paragraph:

Referring to Fig. 5, surface 90 of conductive polyethylene oxide coat 70 is in continuous, direct contact with the adjacent body tissue 30, resulting in a very good interface 20. Conductive polymer coat 70 also completely fills and permeates the porous structure 112 resulting in the realization of the full beneficial potential of the IrOx layer 80.

In the Claims

Please cancel claims 8-25 without prejudice and disclaimer, and add new claims 26-48, as follows:

26. (New) The composition of claim 1 wherein the ionically conductive polymeric composition comprises an electrically conductive ionic species.

27. (New) The composition of claim 1 wherein the ionically conductive polymeric composition further comprises antithrombotic, anticoagulant, anti-infection or thrombolytic agents, or a combination thereof.

28. (New) The composition of claim 1 wherein the ionically conductive polymeric composition further comprises plasticizer salts.

29. (New) The composition of claim 1 wherein the polymer is selected from the group consisting of polyethylene oxide, polyethylene terpthalate, hydrogels and polyacrylates.

30. (New) The composition of claim 6 wherein the inorganic filler is selected from the group consisting of high surface area alumina and high surface area silica.

31. (New) An ionically conductive polymeric composition comprising:
a biocompatible polymer; and
a biocompatible ionic carrier.

32. (New) The composition of claim 31 further comprising a solvent.

33. (New) The composition of claim 31 wherein the polymer is selected from the group consisting of polyethylene oxide, polyethylene terpthalate, hydrogels and polyacrylates.

34. (New) The composition of claim 31 wherein the composition further comprises an inorganic filler.

35. (New) The composition of claim 34 wherein the inorganic filler is selected from the group consisting of high surface area alumina and high surface area silica.

36. (New) The composition of claim 31 wherein the ionically conductive polymeric composition further comprises plasticizer salts.

37. (New) An ionically conductive polymeric composition comprising:

5-10% polyethylene oxide; and

1-2% NaCl.

38. (New) The composition of claim 37 further comprising a 50:50 ratio alcohol:water.

39. (New) The composition of claim 37 wherein the polyethylene oxide having a molecular weight from about 100 kd to about 5,000 kd.

40. (New) The composition of claim 37 wherein the composition further comprises an inorganic filler.

41. (New) The composition of claim 40 wherein the inorganic filler is selected from the group consisting of high surface area alumina and high surface area silica.

42. (New) The composition of claim 37 wherein the ionically conductive polymeric composition further comprises plasticizer salts.

43 (New) An ionically conductive polymeric composition comprising:

5-10% polyethylene oxide; and

1-2% NaCl

44. (New) The composition of claim 43 further comprising alcohol.

45. (New) The composition of claim 43 wherein the composition further comprises an inorganic filler.

46. (New) The composition of claim 45 wherein the inorganic filler is selected from the group consisting of high surface area alumina and high surface area silica.

47. (New) The composition of claim 43 wherein the polyethylene oxide having a molecular weight from about 100 kd to about 5,000 kd.

48. (New) The composition of claim 43 wherein the ionically conductive polymeric composition further comprises plasticizer salts.

Page 38, please replace the "ABSTRACT OF THE DISCLOSURE", and insert therefore the following:

--ABSTRACT OF THE DISCLOSURE

An ionically conductive polymeric composition is disclosed. The composition is especially useful for coating an implantable hot can defibrillator electrode. The polymeric composition, for example, polyethylene oxide containing NaCl or a similar ionic medium, can be used to coat and fill the pores of a high surface area electrode to provide a continuous ionic network from the can to the adjacent body tissue. The conductive polymeric composition is biocompatible, chemically and mechanically stable and does not dissolve or leach out over the useful lifetime of the defibrillator. A hot can defibrillator employing the polymeric coating avoids development of high polarization at the can/tissue interface and maintains a more uniform defibrillation threshold than conventional implantable defibrillators, thus increasing the feasibility of pectoral implantation, particularly in a "dry pocket" environment.--

The above amendments are not believed to add new matter from that disclosed in the original parent application.

REMARKS

During prosecution of the parent application, U.S. Serial No. 09/042,255 filed 3/13/98, in the Requirement for Restriction communication mailed July 19, 1999, the Examiner restricted the subject matter into four Groups. Group I is drawn to an ionically conductive polymeric composition, claims 1-7. Group II is drawn to an electrode coating, claims 8-13. Group III is drawn to an implantable cardiac stimulator, claims 14-16. Group IV is drawn to a method of making an implantable cardiac stimulator, claims 17-25, classified in class 29, subclass 825. Claims 8-25 have now been canceled without prejudice and disclaimer, and applicant reserves the right to claim the subject matter contained therein in this and other applications.

Claims 1-7 and 26-48 are now pending.

Applicant respectfully requests that drawing corrections be considered and entered as presented by the attached red-lined photocopies of the drawings. Formal drawings are submitted reflecting these amendments. Applicant believes that these drawing amendments merely embodies the correction of formal matters without changing the scope of the claims, drawings, or Specification.

Applicant respectfully requests consideration and entry of the Specification amendments to more clearly point out the elements of the Figures.

The application filing fee as calculated on the application transmittal sheet reflects the amendments to the claims described above.

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number if there are any questions regarding this Response or if prosecution of this application may be assisted thereby.

Respectfully submitted,

M. Zafar A. Munshi

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 371-2157

Date 8/3/01 By

Paul J. Fordenbacher
Reg. No. 42,546

"Express Mail" mailing label number: EL671640365US
Date of Deposit: August 3, 2001
This paper or fee is being deposited on the date indicated above with the United States Postal Service pursuant to 37 CFR 1.10, and is addressed to The Commissioner for Patents, Box Patent Application, Washington, D.C. 20231.

Docket No. 01080.165US3
WD #389816

Marked up Version of Amended Specification Paragraphs

AN IONICALLY CONDUCTIVE POLYMERIC COMPOSITION
Applicant: M. Zafar A. Munshi
Serial No.:

In the Specification

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The paragraph beginning on page 18, line 22 is amended as follows:

An improvement over known titanium electrodes, including "hot can" electrodes such as that disclosed in the '607 patent, is provided by the present invention by increasing the effective surface area of the electrode, overlaying this roughened, or enhanced, substrate with a thin coating comprising a conductive polymer. [FIG. 2A illustrates a cross-sectional view of] FIG. 2B illustrates, in partial cut-away, view of the tissue/can interface of a polymer coated can 1 in accordance with the present invention. A conventional Defibrillator unit 1, having a titanium housing 10 coated with an insulative material 12, such as parylene, and an uncoated area or window 14 in coating 12, includes an etched, or otherwise surface area enhanced, titanium surface 100 that functions as one of the stimulus electrodes. Over titanium surface 100 is a high surface area noble metal layer 106. Permeating and overlying noble metal layer 106 is a conductive polymeric coating 70 that has a smooth outer surface 90, as best show in enlarged detail in FIG. 2A. The coated unit is prepared as follows. First, the surface area is increased by highly etching the titanium can surface with acid, such as oxalic acid at 80EC for one to two hours, as previously described in U.S. Pat. No. 5,645,030 ("the '030 patent") for transvenous electrodes, the disclosure of which is incorporated herein by reference. In this way, the surface area of the substrate is increased by as much as 20 times over the planar surface area of the original can. Next, a very thin stable coating of electrode material, such as platinum, is deposited on the etched substrate in such a way that the platinum layer literally follows the contours of the etched pattern, or porous structure. This is accomplished by ion beam deposition, sputtering, evaporation, plasma spraying, chemical methods, or other means. Care is taken to make the platinum layer continuous but not so thick that it fills in the voids, or completely blocks the etched pattern with the coating material. In this way a high surface area platinum is generated which retains a great deal of the original surface roughness. Although the preferred coating

which retains a great deal of the original surface roughness. Although the preferred coating material is platinum, another similarly stable electrode material, such as ruthenium, rhodium, palladium, osmium, iridium, or an alloy of any of those metals, could be substituted with good results.

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The paragraph beginning on page 30, line 6 is amended as follows:

Referring to Fig. 5, surface 90 of conductive polyethylene oxide coat 70 is in continuous, direct contact with the adjacent body tissue 30, resulting in a very good interface 20. Conductive polymer coat 70 also completely fills and [permeates, the porous structure 40] permeates the porous structure 112 resulting in the realization of the full beneficial potential of the IrOx layer 80.

MARKED UP VERSION OF ABSTRACT

AN IONICALLY CONDUCTIVE POLYMERIC COMPOSITION
Applicant: M. Zafar A. Munshi
Serial No.: Unknown

An ionically conductive polymeric composition [for coating a hot can defibrillator electrode] is disclosed. The composition is especially useful for coating an implantable hot can defibrillator electrode. [A] The polymeric [coating,] composition, such as polyethylene oxide containing NcCl or a similar ionic medium, [coats and fills] can be used to coat and fill the pores of a high surface area electrode to provide a continuous ionic network from the can to the adjacent body tissue. [In certain embodiments, the underlying high surface area, porous electrode is made by chemically etching a smooth electrode surface, such as that of a conventional titanium housing, followed by applying a thin coating of a noble metal such as platinum. In other embodiments, a noble metal or an oxide thereof, such as platinum black or iridium oxide, is applied to a titanium housing to form a porous, high surface area electrode. The conductive polymeric coating is then applied over the porous noble metal or metal oxide.] The [electrically] conductive polymeric [material] composition is biocompatible, chemically and mechanically stable and does not dissolve or leach out over the useful lifetime of a defibrillator. A hot can defibrillator employing the [new] polymeric coating avoids development of high polarization at the can/tissue interface and maintains a more uniform defibrillation threshold than conventional implantable defibrillators, thus increasing the feasibility of pectoral implantation, particularly in a "dry pocket" environment.

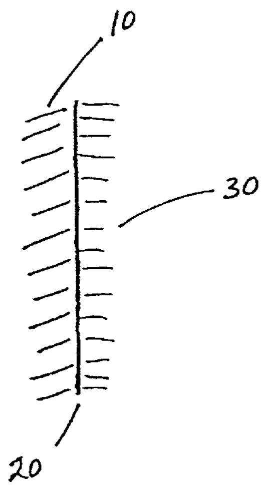

FIG. 1A
(Prior Art)

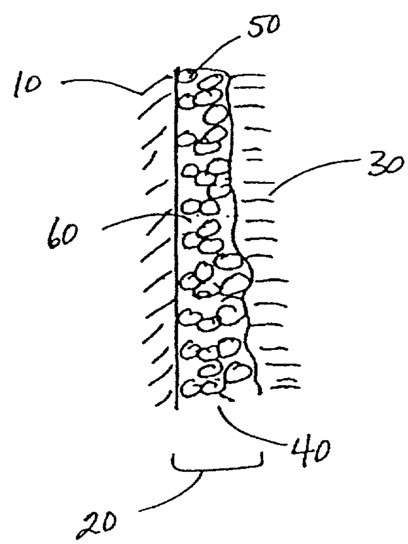

FIG. 1B
(Prior Art)

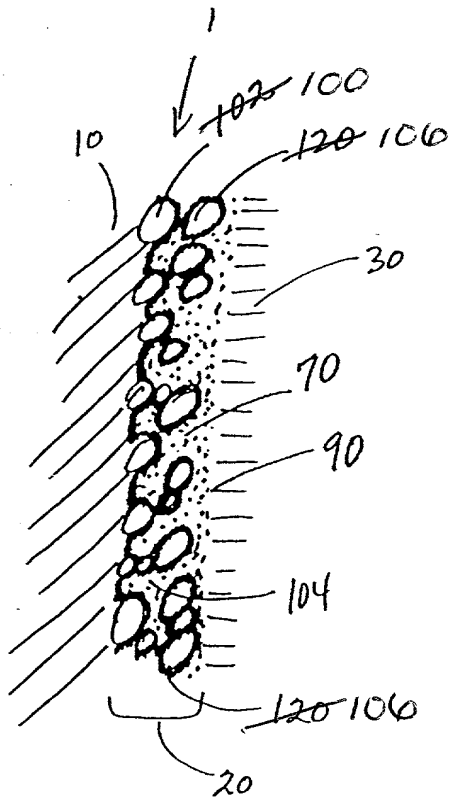

FIG. 2A

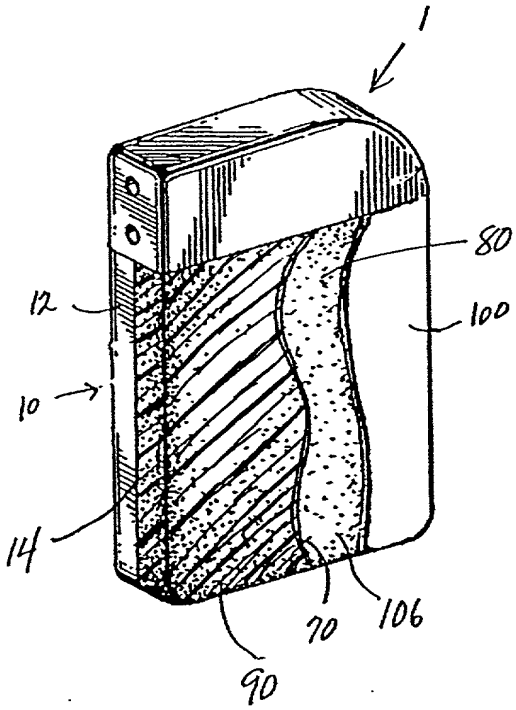

FIG. 2B

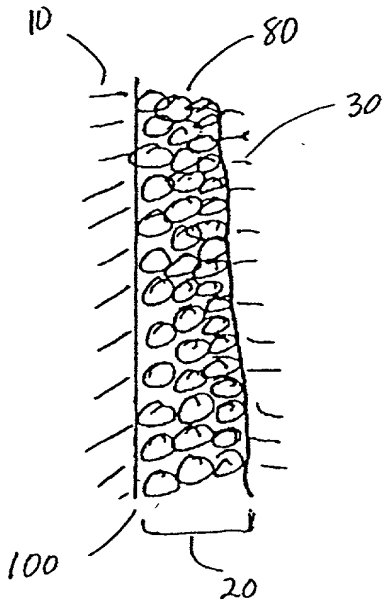

FIG. 4
(Prior Art)

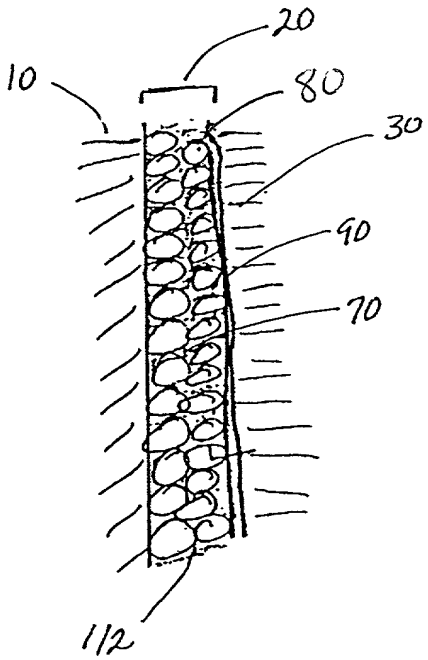

FIG. 5